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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,090	07/22/2003	George A. Scheele	JHU1710-4	8783

28213 7590 05/17/2007

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EXAMINER	
LE, EMILY M	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
05/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,090	SCHEELE ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/22/03, 10/31/06 and 2/21/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-63 and 70-72* is/are pending in the application.

4a) Of the above claim(s) *50,51,55,56,58 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-49,52-54,57,60-63 and 70-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/02/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of A method of treating viral infection, HSV-1, in the reply filed on October 31, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

2. Claims 1-27 and 64-69 are cancelled. Claims 70-72 are added. Claims 28-63 and 70-72 are pending. Claims 50-51, 55-56 and 58-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected viral species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 31, 2006. Claims 28-49, 52-54, 57, 60-63 and 70-72 are under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 28-49, 52-54, 57, 60-63 and 70-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Nature of the Invention:

The claimed invention is directed at a method of treating or preventing viral infection in a mammal that is infected or suspected of being infected by an envelope virus or a microorganism that enters a cell of the mammal by endocytosis comprising the administration of the a cholesterol-sequestering agent.

Lines 1-16, page 7 of the specification provides a detailed discussion of the nature of the invention. At the cited passage, it is disclosed that because cholesterol-sequestering agent may cause lysis of envelope virus, the removal of cholesterol from the viral membrane with a cholesterol-sequestering agent will disrupt the ordered

structure of membrane elements and destroys the integrity of the membrane itself—leading to disruption of the viral membrane and leakage of viral contents.

The Breadth Of The Claims:

With the exception of claims 48-49 and 71-72, which limit the envelope virus to herpes virus (herpes virus 1), the claims are not limiting to a specific envelope virus. Thus, with regard to the type of virus, the full breadth of the claims encompasses all envelope viruses. Examples of envelope viruses include HIV, hepatitis virus, influenza virus...etc.

Additionally, it is noted that the claims recite a method of preventing an infection. The broadest reasonable interpretation of the term infection merely requires that one microorganism gain entry into the cells of a host.

Hence, it can be summarized that the claimed invention is directed at the administration of a cholesterol-sequestering agent to disrupt the viral membrane and leakage of viral contents in a mammal infected or suspected of being infected by an envelope virus, and to prevent viral entry into the cells of the mammal.

The Presence Or Absence Of Working Examples:

The specification is fatally defective in this regard. The specification does not contain any working examples.

The Amount Of Direction Or Guidance Presented:

The specification is also totally defective in this regard. The specification does not contain any discussion or evidence relating to the efficacy of the claimed invention.

The State Of The Art and The Predictability Or Unpredictability Of The Art:

Prior to the filing date of the instant patent application, the art recognizes that cyclodextrin, a cholesterol-sequestering agent, has potent anti-herpes activity in vitro;[1] however, the art does not recognize the therapeutic, in vivo or dermal, use of cyclodextrin to treat herpes or infection by other envelope viruses or any microorganism that enters a cell of the mammal by endocytosis. Rather, in approximately the five years following the filing of the instant patent application, including the priority filing date, it is noted that Applicant has not been able to demonstrate that the administration of a cholesterol-sequestering agent treats or prevents viral infection in a mammal infected or suspected of being infected with an envelop virus. This finding is substantiated by Applicant's statement,[2] wherein Applicant notes that "if it [cyclodextrin] works [as a HIV microbiocide]." This statement evidences that Applicant has yet to determine if cyclodextrin is effective against envelope viruses, including HIV. This statement further evidences that the art is unpredictable. In the instant case, the art demonstrates that *in vitro* efficacy do not readily correlate or extrapolate *in vivo*.

Quantity Of Experimentation Necessary:

In the absence of any working examples and any direction or guidance from the specification, the skilled artisan would not be able to practice the claimed invention without an undue burden of experimentation. Additionally, the skilled artisan would have an undue burden of experimentation due to the lack of predictability noted the art.

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[1] Wallace et al. US. Provisional Application No. 60/366429, filed March 21, 2002, as shown on US PreGrant Patent No. 20030220294.
[2] Exploring the potential of HIV microbiocides. NCRR Reporter (cover Story), Winter 2007, Vol. 31, No. 1.

In the instant case, the skilled artisan would have to experiment with every aspect of the claimed invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 28-49, 52-54, 57, 60-63 and 70-72 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/637793 (U.S. PreGrant Patent No. 20050015847). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instantly claimed invention is directed at a method of treating or preventing viral infection in a mammal that is infected or suspected of being infected by an envelope virus comprising the administration of the a cholesterol-sequestering agent.

The invention claimed in the conflicting patent application is directed to: a method of preventing viral infection in a mammal that is infected or suspected of being infected by an envelope virus comprising the administration of a cholesterol-sequestering agent.

The difference between the claims is: the broadest claim of the conflicting patent application limits the cholesterol-sequestering agent to beta-cyclodextrin, whereas, the broadest claim of the instant patent application is not limiting to a specific cholesterol-

sequestering agent. However, the species of cholesterol-sequestering agent recited in the conflicting patent application anticipates the genus of cholesterol-sequestering agent recited in the instant patent application.

The other difference noted is: the broadest claim of the conflicting patent application limits the administration step to a dermal protocol; whereas, the broadest claim of the instant patent application is not limiting to a specific administration method. However, the species of administration method recited in the conflicting patent application anticipates the genus of administration method recited in the instant patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 28-49, 52-54, 57, 60-63 and 70-72 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/605037(U.S. PreGrant Patent No. 20070088000). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instantly claimed invention is directed at a method of treating or preventing viral infection in a mammal that is infected or suspected of being infected by an envelope virus comprising the administration of the a cholesterol-sequestering agent.

The invention claimed in the conflicting patent application is directed to: a method of treating an infection in a mammal that is infected or suspected of being infected by an envelope virus comprising the administration of beta-cyclodextrin.

The difference between the claims is: Claim 1 of the conflicting patent application is limiting to the administration of beta-cyclodextrin, which is a cholesterol-sequestering agent; whereas, the broadest claim of the instant patent application is not limiting to a specific cholesterol-sequestering agent. However, the species of cholesterol-sequestering agent recited in the conflicting patent application anticipates the genus of cholesterol-sequestering agent recited in the instant patent application.

The other difference is: claim 1 of the conflicting patent application is not limiting to an envelope virus, whereas, the claims of the instant patent application is limited envelope viruses. However, it is noted that claim 3 of the conflicting patent application limits the virus of claim 1 to an envelope virus. Hence, claim 1 of the conflicting patent application is also directed to encompass envelope viruses.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M. Le
Patent Examiner
Art Unit 1648

5/08/07

E.Le